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| EXAMINER |
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ALSTRUM ACEVEDO, JAMES HENRY

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| ART UNIT | PAPER NUMBER |
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1616

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08/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,571

Applicant(s)

BATYCKY ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 140-144, 146-150, 153 and 156-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 140-144, 146-150, 153, and 156-173 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 140-144, 146-150, 153, and 156-173 are pending. Applicants previously cancelled claims 1-139 and 145. Applicants have newly cancelled claims 151-152 and 154-155. Applicants' petition filed on November 9, 2006 requesting entry of an amendment after Final rejection was granted on January 4, 2007. This office action is necessitated by the granted amendment. Receipt and consideration of Applicants' appeal brief, filed April 25, 2007, the arguments/remarks, and amended claims therein are acknowledged.

Moot Rejections/objections

All rejections and/or objections of claims 151-152 and 154-155 cited in the previous office action mailed on April 6, 2006 **are moot**, because said claims have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 140-144, 146-150, 152, and 156-171 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 140 is indefinite because it claims a method of administering an amount of particulate epinephrine of "at least about 50 micrograms" possessing a fine particle fraction of less than 5.6 microns of "at least about 45 percent." The phrase "at least about" is indefinite, because it simultaneously claims two different ranges. An ordinary skilled artisan would be

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unable to ascertain whether the required amount of epinephrine administered is at least 50 micrograms or about 50 micrograms. Similarly, an ordinary skilled artisan would be unable to ascertain whether the required fine particle fraction (FPF) is at least 45 percent or about 45 percent. Appropriate correction is required.

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 140-144, 154, and 156-160 under 35 U.S.C. 102(e) as being anticipated by Tarara et al. (US 2005/0074498) **is withdrawn**, per Applicants' claim amendments entered by petition.

Response to Arguments

Applicant's arguments, see page 4 of the appeal brief, filed April 25, 2007, with respect to the rejection of claims 140-144, 154, and 156-160 under 35 U.S.C. 102(e) as being anticipated by Tarara et al. (US 2005/0074498) have been fully considered and are persuasive. The rejection of claims 140-144, 154, and 156-160 under 35 U.S.C. 102(e) as being anticipated by Tarara et al. (US 2005/0074498) has been withdrawn.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 140-144, 153, and 156-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) in view of Slutsky et al. (U.S. Patent No. 6,102,036).

Applicant Claims

Applicants claim a method for treating a patient in need of epinephrine comprising administering spray-dried particles from a dry powder inhaler to the respiratory system of a patient in a single, breath-activated step, the particles comprising (a) epinephrine or a salt thereof and, (b) at least one pharmaceutically acceptable excipient, wherein the particles administered to

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the patient comprise at least about 50 micrograms of epinephrine, have a tap density of less than 0.4 g/cm³, and possess a fine particle fraction of less than 5.6 microns of at least about 45 percent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara were set forth on pages 3-5 of the office action mailed on April 6, 2006. Slutsky teaches a breath activated inhaler, which may contain a single dose of a powdered medicament, which is intended to be inhaled by the patient in a single breath (title; abstract; col. 4, lines 47-49; col. 6, lines 27-62; col. 8, lines 50-55 and 60-62; col. 9, lines 25-30; col. 10, line 48 through col. 13, line 42, especially col. 12, lines 38-59). Slutsky teaches an alternative breath-activated inhaler capable of delivering a large dose of powdered medicament in a single breath (col. 12, lines 38-59).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Tarara lacks the explicit teaching that powdered formulations are delivered in a single breath actuated step. This deficiency is cured by the teachings of Slutsky.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious to a person of ordinary skill at the time of the instant invention to combine the teachings of Tarara and Slutsky, because Tarara teaches powdered pharmaceutical formulations for inhalation administration and Slutsky teaches breath-

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activated inhalers for the administration of powdered medicaments. It would also have been obvious to combine the teachings of Tarara and Slutsky, because as taught by Slutsky, use of Slutsky's invented inhaler would allow one to deliver a large dose in a single breath. An ordinary skilled artisan would have been motivated to utilize an inhaler capable of delivering a therapeutically effective dose in a single breath, because this would clearly improve patient compliance. Patient compliance would clearly be improved, because one would need fewer administrations to deliver a therapeutically effective dose contained in an inhaler. Regarding the amount of epinephrine delivered, Applicants' claims have no maximum limit on the amount of epinephrine delivered, merely that at least 50 micrograms is delivered. The combination of Tarara's invented compositions with Slutsky's invented inhaler would reasonably be expected to deliver at least 50 micrograms of epinephrine, because one can modify the dosage of epinephrine present in an inhaler to ensure the delivery of a therapeutically effective amount of epinephrine and Slutsky's inhaler permits delivery of an entire dose in a single breath. Therefore, an ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 140-144, 153-154, and 156-160 have been considered but are moot in view of the new ground(s) of rejection.

Claims 161-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) in view of Slutsky et al. (U.S. Patent No. 6,102,036) as applied to claims 140-144, 153, and 156-160 above, and further in view of Physicians' Desk Reference (PDR, page 1236) (already of record).

Applicant Claims

Applicants claim a method as described above in the instant office action wherein epinephrine is administered to treat anaphylaxis, edema, bronchoconstriction, bronchospasm, and airway constriction.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara were set forth on pages 3-5 of the office action mailed on April 6, 2006. The teachings of Slutsky were set forth above in the instant office action. The teachings of the PDR were set forth on page 7 of the office action mailed on April 6, 2006.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Tarara lacks the teaching of a method of treatment wherein epinephrine is administered to treat anaphylaxis, edema, bronchoconstriction, bronchospasm, and airway constriction. This deficiency is cured by the teachings of the PDR.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tarara/Slutsky and the PDR, because Tarara teaches pharmaceutical preparations wherein the perforated microstructures may comprise adrenaline (i.e. epinephrine) active agent and the PDR describes known treatments which utilize epinephrine to treat anaphylaxis, angioedema, and relax the bronchial smooth muscles. A skilled artisan would have been motivated to combine the prior art references, because the PDR is a well-known medical reference consulted by physicians and other medical professionals to determine which medicaments are appropriate to treat which conditions or disorders. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art references, because Tarara teaches pharmaceutical compositions comprising adrenaline and the PDR teaches treatments in which the administration of adrenaline is appropriate, such as in the treatment of anaphylaxis, bronchoconstriction, bronchospasm, etc. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 161-162 have been considered but are moot in view of the new ground(s) of rejection.

Claims 140-143, 146-150, 159, 160, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 2003/0215512) in view of Tarara et al. (US 2005/0074498) and Slutsky (U.S. Patent No. 6,102,036).

Applicant Claims

Applicants claim a method as described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara were set forth on pages 3-5 of the office action mailed on April 6, 2006. The teachings of Slutsky were set forth above in the instant office action. The teachings of Foster were set forth on pages 8-10 of the office action mailed on April 6, 2006.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Foster lacks the teaching of compositions having a tap density of less than 0.4 g/cm^3 , which is cured by the teachings of Tarara. Foster lacks the teaching of administration in a single breath-activated step. This deficiency is cured by the teachings of Slutsky.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant application to combine the teachings of Foster and Tarara/Slutsky, because all inventors teach compositions suitable for inhalation pulmonary administration of active agents. A skilled artisan would have been motivated to combine the teachings of Foster and Tarara, because Tarara's compositions provide teachings of desirable physical characteristics of aerodynamically light particles especially suitable for inhalation administration. An ordinary skilled artisan cognizant of the teachings of Slutsky would be motivated to utilize Slutsky's breath-activated

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inhaler to improve patient compliance and facilitate delivery of a particulate pharmaceutical formulation in the fewest number of administrations. A skilled artisan would have had a reasonable expectation of success upon combination both Tarara and Foster teach adrenaline-containing (i.e. epinephrine) compositions designed for inhalation pulmonary administration. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 161-162 have been considered but are moot in view of the new ground(s) of rejection.

Claim 171 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) in view of Slutsky et al. (U.S. Patent No. 6,102,036) as applied to claims 140-144, 153, and 156-160 above, and further in view of Radhakrishnan (U.S. patent 5,049,389) (already of record).

Applicant Claims

Applicants claim a method as described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara were set forth on pages 3-5 of the office action mailed on April 6, 2006. The teachings of Slutsky were set forth above in the instant office action. The

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teachings of Radhakrishnan were set forth on page 10 of the office action mailed on April 6, 2006.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Tarara lacks the teaching of compositions releasing active agents in a sustained manner, which is cured by the teachings of Radhakrishnan.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Tarara and Radhakrishnan, because both inventors teach particulate compositions comprising epinephrine, which is intended for inhalation administration. A skilled artisan would have been motivated to combine the teachings of Tarara and Radhakrishnan to obtain sustained release compositions wherein the active drug and excipients do not crystallize within the liposome and which do not undergo sedimentation when suspended. A person of ordinary skill at the time of the instant invention would have had a reasonable expectation of success upon combination of the prior art references, because both inventors teach particular compositions for inhalation comprising adrenaline. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 161-162 have been considered but are moot in view of the new ground(s) of rejection.

Claims 163-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2005/0074498) in view of Slutsky et al. (U.S. Patent No. 6,102,036) as applied to claims 140-144, 153, and 156-160 above, and further in view of Warren et al. (*Clin. Pharmacol. Ther.*, 1986, 40(6), 673-678) (already of record).

Applicant Claims

Applicants claim a method as described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara were set forth on pages 3-5 of the office action mailed on April 6, 2006. The teachings of Slutsky were set forth above in the instant office action. The teachings of Warren were set forth on pages 11-12 of the office action mailed on April 6, 2006.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Tarara lacks the express teaching of Cmax and Tmax of different administration routes, specifically inhalation administration vs. non-intravenous injection.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

A person of ordinary skill in the art at the time of the instant invention would have been able to obtain information on Warren et al.'s studies showing that the administration of inhaled adrenaline would lead to a shorter time for adrenaline blood plasma levels to reach a maximum concentration as a predictor of what one would expect upon inhalation administration of Tarara's pharmaceutical formulations. A skilled artisan would have known that drug blood plasma levels are a measure of the systemic absorption of a pharmaceutical agent and that said agent would therefore be acting systemically. Based on Warren's data, a person of ordinary skill in the art at the time of the instant invention would have been motivated to administer epinephrine to a patient and would have had a reasonable expectation that said drug administered by inhalation would result in maximal adrenaline blood serum levels in a shorter period of time when compared to non-intravenous injection routes of administration. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 161-162 have been considered but are moot in view of the new ground(s) of rejection.

Claims 172-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US 2003/0215512) in view of Tarara et al. (US 2005/0074498) and Slutsky

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(U.S. Patent No. 6,102,036) as applied to claims 140-143, 146-150, 159, 160, and 162 above, in further view of the *Drug Information Handbook* (1993) ("DIH").

Applicant Claims

Applicants claim a method as described above in the instant office action.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Tarara were set forth on pages 3-5 of the office action mailed on April 6, 2006. The teachings of Slutsky were set forth above in the instant office action. The teachings of the DIH were set forth on page 12 of the office action mailed on April 6, 2006.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Tarara lacks the express teaching of the teaching of a composition comprising epinephrine bitartrate.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art to combine the teachings of Tarara/Foster with the DIH, because the DIH is a standard reference used in the pharmaceutical art and the other two prior art references teach pharmaceutical compositions comprising epinephrine. A skilled artisan would have been motivated to combine the teachings of the DIH with those of Tarara and Foster, because epinephrine is a known active agent and epinephrine bitartrate is a common salt of said active used in commercially available

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pharmaceutical formulations. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art references, because Tarara, Foster, and the DIH teach compositions wherein the active is epinephrine, and the bitartrate salt of adrenaline is commonly used in pharmaceutical formulations. Regarding the amount of active agent, Foster teaches an overlapping range for the amount (i.e. about 0.05% to about 99.0% by w/w). In addition, it would have been readily apparent to a skilled artisan per the teachings of Foster that the remainder of the composition would comprise glass-forming excipient (i.e. sodium tartrate) and other additives (e.g. leucine). The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 161-162 have been considered but are moot in view of the new ground(s) of rejection.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 140-143, 151, 154, 159, and 160 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 9, 10, 12, 14, 18, 25, and 27 of copending Application No. 10/818,902 in view of Maa et al. (U.S. patent 6,284,282) **is moot**, because the cited claims of copending '902 have been cancelled.

Conclusion

Claims 140-144, 146-150, 153, and 156-173 are rejected. No claims are allowed.

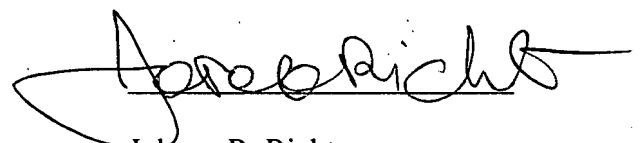
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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